UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

AGA Medical Corp., **Plaintiff,** **v.** **W. L. Gore & Associates, Inc.,** **Defendant.**	No. 0:10-cv-3734 (JNE/JSM) **GORE'S MEMORANDUM IN OPPOSITION TO AGA'S MOTION TO COMPEL IMMEDIATE DISCOVERY CONCERNING THE GORE SEPTAL OCCLUDER DISCLOSED AT THE 8TH INTERNATIONAL WORKSHOP ON INTERVENTIONAL PEDIATRIC CARDIOLOGY IN MILAN, ITALY**

I. INTRODUCTION

AGA's motion to compel (Dkt. 45) seeks to compel production of irrelevant documents and improperly seeks to turn discovery into a fishing expedition to obtain information about non-accused medical devices. The single nitinol wire GORE® HELEX® Septal Occluder is the only device that AGA has accused of infringing the '738 patent in this lawsuit. AGA does not identify any legal basis for its argument that Gore should be compelled to produce discovery concerning medical devices other than the accused GORE® HELEX® Septal Occluder. Specifically, the subject of the present motion is a new multi-wire septal occluder medical device that was in development in April 2011 and was the subject of a presentation in April of 2011 at the 8th International Workshop on Interventional Pediatric Cardiology ("IPC") in Milan, Italy ("the Milan development device"). That non-accused medical device is simply not relevant here. In

addition, AGA's overly broad discovery requests may embrace other development devices that may be considered "five-wire" or "multi-wire" septal occluder devices and also are not relevant here.

Importantly, AGA already has a forum in which to obtain the discovery that it seeks here. The Milan development device was not approved for use in Europe until June 2011 and is known under the trade name of GORE® Septal Occluder. Gore has already brought a Declaratory Judgment Action in the District of Delaware regarding the GORE® Septal Occluder medical device that is the subject of the present motion. (Case No. 1:11-cv-00539 (D. Del.)) ("the Delaware Action"). That declaratory judgment action involves different issues than the present action. Not only does the Delaware action concern a different medical device (GORE® Septal Occluder vs. HELEX® Septal Occluder) but the Delaware action involves an additional patent (U.S. Pat. No. 5,725,552) that is not asserted in the instant action ("the Minnesota Action"), and an additional party (AGA Medical Holdings). The Delaware Action is the proper forum for AGA to seek discovery regarding the new GORE® Septal Occluder medical device, and injecting that new medical device into the Minnesota action when the first filed complaint about the GORE® Septal Occluder medical device is in Delaware would needlessly complicate this case and slow its progress towards trial. Accordingly, AGA's motion to compel should be denied.

II. FACTUAL BACKGROUND

A. AGA has consistently limited its specific accusations of patent infringement to the GORE® HELEX® Septal Occluder medical device.

In its Complaint, AGA specifically identified only the HELEX® Septal Occluder medical devices as infringing claims 20, 23, 25, 27, and 30 of U.S. Pat. No. 5,944,738 ("the '738 patent").[1] (Dkt. 1 ¶ 8.) The GORE® HELEX® Septal Occluder comprises an ePTFE membrane attached to a single nitinol wire. (*See* Goodin Ex.[2] 1, Gore's Preliminary Noninfringement Claim Chart.) AGA has consistently directed its infringement allegations to only the HELEX® Septal Occluder device as the case proceeded through initial discovery and preliminary infringement contentions. (*See* Dkt. 17, Rule 26(f) report; Goodin Ex. 2, Plaintiff AGA Medical Corporation's Preliminary Claim Chart.)

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[1] Specifically, AGA's complaint tersely alleges infringement by "occluder products," *generally*, "including without limitation the Gore HELEX occluder." AGA's complaint cannot reach products other than Gore's HELEX® Septal Occluder under *Ashcroft v. Iqbal*, 129 S.Ct. 1937, 1950 (2009) and *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Mere labels and conclusory statements (alleging infringement of Gore's occluder products, generally, beyond HELEX) cannot withstand a Rule 8 challenge. *See Koninklijke Philips Elec. v. The ADS Group*, 694 F. Supp. 2d 246, 251-53 & n.8 (S.D.N.Y 2010); *See also Eurand, Inc. v. Mylan Pharma., Inc.*, 266 F.R.D. 79, 84 (D. Del. 2010) ("It is improper to use discovery in search of a factual predicate required to be pled in the first instance.").

[2] "Goodin Ex." as used herein refers to the exhibits to the Declaration of Myoka Kim Goodin in Support of Gore's Memorandum in Opposition to AGA's Motion to Compel Immediate Discovery Concerning The Gore Septal Occluder Disclosed At The 8th International Workshop On Interventional Workshop On Interventional Pediatric Cardiology in Milan, Italy, filed concurrently herewith.

B. AGA's counsel seeks to compel discovery concerning devices other than the GORE® HELEX® Septal Occluder that have not been accused of infringement in this case.

AGA's counsel had lodged broad discovery requests that go far beyond the GORE® HELEX® Septal Occluder medical devices, and instead reach the now commercialized and new GORE® Septal Occluder medical device, as well as potentially other upstream and non-commercialized medical devices. Specifically, in April 2011, AGA requested documents from Gore relating to undefined "multi-wire septal occlusion devices" and "5-wire occluder frame designs." (Bremer Ex.[3] 9, Plaintiff AGA Medical Corporation's Second Set of Requests for Production of Documents to Defendant W.L. Gore & Associates (Nos. 30-37) (Dkt. 48-9).) Gore objected to AGA's document requests in part as being "vague and ambiguous" because of the undefined reference to "five-wire" or "multi-wire" occluder devices, which may potentially embrace other developmental occluder devices that may be considered "five-wire" or "multi-wire," which are not and may never be commercialized. (Bremer Ex. 12, Gore's Objections and Responses to AGA's Second Set of Requests For Production of Documents (Nos. 30-37) (Dkt. 48-12).)

In early May, AGA also amended its Notice of 30(b)(6) Deposition of Gore to add a new Rule 30(b)(6) deposition topic seeking testimony regarding a "Gore Five Wire Occluder Device" that was disclosed in Milan. (Bremer Ex. 11, AGA's

[3] "Bremer Ex." as used herein refers to the exhibits to the Declaration of Dennis C. Bremer (Dkt. 48) filed on July 1, 2011 in support of AGA's Motion to Compel Immediate Discovery Concerning the Gore Septal Occluder Disclosed At the 8th International Workshop on Interventional Pediatric Cardiology in Milan, Italy (Dkt. 45).

Amended Notice of Rule 30(b)(6) Deposition ("the Amended Deposition Notice") at 22 (Topic 16) (Dkt. 48-11).) In that discovery request, the phrase "Gore Five Wire Occluder Device" was defined as "the Gore multi-wire occluder frame device disclosed at the 8th International Workshop on Interventional Pediatric Cardiology, held in Milan, Italy on March 31-April 2 of 2011." AGA sought to add this topic concerning devices other than HELEX® Septal Occluder about a week before the previously scheduled deposition concerning HELEX® Septal Occluder.

While AGA's document requests were broadly directed to undefined "multi-wire septal occlusion devices" and "5-wire occluder frame designs," we understand that AGA has now narrowed the scope of their discovery requests in the present motion so that it is limited to the specific developmental septal occluder device that was discussed at the Milan conference and later received CE mark approval in June.

AGA has not raised infringement allegations against any multi-wire or five-wire septal occluder device in this case. The accused HELEX® Septal Occluder device differs in many aspects from any such multi-wire device, including the Milan development device. For one, the HELEX® Septal Occluder comprises only a single nitinol wire, while the Milan development device has multiple wires. Also, unlike the HELEX® Septal Occluder device, the Milan development device is not comprised of solid nitinol wires.

C. Gore properly objected to AGA's discovery requests within the time allowed for by the Federal Rules of Civil Procedure.

On May 11, 30 days after being served with AGA's document requests, Gore objected to AGA's discovery requests regarding the multi-wire and 5-wire occluder devices. (Bremer Ex. 12, Gore's Objections and Responses to AGA's Second Set of Requests For Production of Documents (Nos. 30-37) (Dkt. 48-12).) The scope of these broadly written requests was unclear because the scope of the terms "multi-wire occluder" and "5-wire occluder" was not defined. At the time, Gore had no such devices approved for sale anywhere in the world. Since that date, the GORE® Septal Occluder medical device received CE mark approval in the European Union in June. (*See* Bremer Ex. 13, Declaratory Judgment Complaint at ¶28 (Dkt. 48-13).) Gore thus rightfully informed AGA that its requests seek "documents and things relating to clinical studies and other activities that, pursuant to 35 U.S.C. § 271(e)(1), do not constitute acts of infringement" (Bremer Ex. 12, General Objection No. 11 at 4 (Dkt. 48-12)) and "are overly broad, unduly burdensome, and unlikely to lead to the discovery of admissible evidence to the extent it seeks documents and things relating to products that have not been accused of infringement in this case, and for which AGA has not provided infringement contentions" (*see* Bremer Ex. 12, Responses to Request Nos. 30-33, 35 at 4-8 (Dkt. 48-12)).

On May 16, just five days after being served with the Amended Deposition Notice, Gore similarly objected to producing a 30(b)(6) witness to testify about

devices that have not been accused of infringement in this case. (Bremer Ex. 16, Gore's Objections to Amended Notice of Rule 30(b)(6) deposition (Dkt. 48-16).)

D. Gore received approval in June 2011 to commercialize its new GORE® Septal Occluder product only in Europe.

At the time of AGA's discovery requests, Gore did not have regulatory authorization to commercialize a "five-wire" or "multi-wire" septal occluder device anywhere in the world, including the United States. It could not sell the Milan development device, and it was uncertain when, if ever, the device would be approved. Indeed, the U.S. Food and Drug Administration still has not approved the device for sale in the United States.

However, on June 10, 2011, Gore did receive approval to commercialize the Milan development device in Europe, which is known under the trade name of GORE® Septal Occluder. (Bremer Ex. 13, Declaratory Judgment Complaint at ¶28 (Dkt. 48-13).) Shortly after receiving regulatory approval in Europe and in consideration of a number of events including AGA's past litigious conduct regarding its patents in the United States and around the world, Gore took the affirmative step of filing the Delaware Action to resolve the case or controversy regarding this next generation product, GORE® Septal Occluder medical device. (Bremer Ex. 13, Declaratory Judgment Complaint (Dkt. 48-13).) AGA has litigated its patents not just against Gore, but against other competitors such as Occlutech, around the world. (*See, e.g.*, Goodin Ex. 3, Article regarding AGA lawsuits in Germany and United Kingdom; Goodin Ex. 4 at 95-98, Article regarding AGA lawsuit in Sweden; Goodin Ex.

5, AGA 2009 filing with Securities and Exchange Commission listing AGA's pending patent litigations worldwide.) In addition to AGA's history of numerous patent litigations involving septal occluder devices in general, AGA had requested that Gore stipulate to a waiver of any laches defense with respect to any claim brought by AGA accusing the non-HELEX® Septal Occluder that was discussed at the IPC in Milan, Italy of infringing any of AGA's patents. (Bremer Ex. 13 at ¶¶ 37-39; Bremer Decl. at ¶21 (Dkt. 48-13).)

The Complaint in the Delaware Action includes claims for invalidity and non-infringement of both the '738 patent and U.S. Patent No. 5,725,552 ("the '552 patent"). (Bremer Ex. 13, Declaratory Judgment Complaint at ¶1 (Dkt. 48-13).) On July 8, AGA filed a motion to dismiss, or in the alternative transfer the Delaware Action. That motion remains pending and briefing is incomplete.

Nevertheless, the information about which AGA seeks to compel discovery here, does not relate to issues in this case, but rather relates to the Delaware Action.

III. ARGUMENT

AGA seeks information that is not relevant to the issues properly plead in the Complaint and that are to be decided in this case. The only device that AGA has accused of infringement in this case is the GORE® HELEX® Septal Occluder. AGA has not accused any multi-wire device of infringing its patents, much less the Milan development device that is the subject of the present motion. Issues concerning the Milan development device on which AGA now seeks to compel discovery are currently and

properly pending in the Delaware Action, not in this case. Accordingly, AGA's motion to compel discovery should be denied.

A. Legal Standard

The Court has broad discretion to limit discovery. *Peterson v. Seagate U.S. LLC*, 2009 WL 3430150, at *1 (D. Minn. Oct. 19, 2009). AGA is not entitled to discovery regarding information that is not relevant to any claim or defense at issue in the case. *See* Fed. R. Civ. P. 26(b)(1). Gore, as the party resisting production, bears the burden of establishing that the discovery AGA seeks to compel is not relevant to the case at hand. *Peterson*, 2009 WL 3430150, at *1.

B. The information AGA seeks to compel is not relevant to any claim or defense pending in this case.

Although AGA may discover information about the device it has accused of infringement, the GORE® HELEX® Septal Occluder, AGA cannot properly seek discovery that is not relevant to the case. The Milan development device is not accused of infringement in this case and that device is not relevant to the issues to be resolved here.

AGA is not entitled to discover information to enable AGA to decide if it should assert a claim of infringement regarding other Gore devices. *See Eurand, Inc. v. Mylan Pharma., Inc.*, 266 F.R.D. 79, 84 (D. Del. 2010) ("It is improper to use discovery in search of a factual predicate required to be pled in the first instance."). For example, a court in the District of Minnesota has denied a party's request for discovery related to non-accused future products in hopes of uncovering potential future claims. *See*

Microsoft Corp. v. Multi-Tech Sys., Inc., Civ. No. 00-1412, 2001 U.S. Dist. LEXIS 23155, at *27-*28 (D. Minn. Dec. 14, 2001). In that case, Multi-Tech had accused one of Microsoft's products, MSN Messenger, of infringing Multi-Tech's patent claims. *Id*. at *26. During the pendency of that patent case, Microsoft was in the process of developing a next generation product to replace portions of the accused infringing product. *Id*. at *27. The court denied discovery of Microsoft's continuation product because it was irrelevant to the issues of the case at that point. *Id*. Multi-Tech's supposition that Microsoft's later product might be infringing did not entitle it to go on a fishing expedition to uncover potential future claims.

Similarly here, AGA improperly seeks to use discovery to troll for information about Gore's future products in development despite having had no basis to accuse those devices of infringing the '738 patent. Under the *Microsoft* decision, that is not the proper subject of discovery. *See also Caritas Tech., Inc. v. Comcast Corp*., 2006 US Dist LEXIS 94879, at *14-*15 (E.D. Tex. Feb. 9, 2006) ("[Plaintiff] only has the right to discover information regarding the alleged infringing service, not the right to discover information on whether it should assert a claim of infringement regarding other services."); *Convolve, Inc. v. Compaq Computer Corp*., 223 F.R.D. 162, 165 (S.D.N.Y. 2004) ("Since they are not currently accused, neither the products themselves nor documents related to them need to be produced"); *Funai Elec. Co. v. Orion Elec. Co*., 2002 US Dist LEXIS 14466, at *26-*27 (S.D.N.Y. Aug. 6, 2002) (denying motion to compel documents seeking information on non-accused devices). AGA does not cite a

single case to suggest that medical devices other than the one accused of infringement are relevant and discoverable.

AGA couches the present motion to compel as being focused solely on the Milan development device. That device was discussed during a conference in Milan, Italy in early April 2011, where the presenter Dr. Carmanati discussed the development device's use in an animal study. Importantly, at that time, Gore did not have approval to commercialize the Milan development device that would later be approved for use in Europe in June and is known under the trade name of GORE® Septal Occluder.

Similarly, when AGA served its broad discovery requests relating to any 5 wire or multi-wire septal occluder devices, Gore had not commercialized any such devices. These were upstream potential future medical devices. Likewise, when Gore subsequently served its objections to those requests, Gore still had not commercialized any such devices, which remained upstream potential future medical devices. As such, information regarding these devices was not and are not discoverable. *See Microsoft*, 2001 U.S. Dist. LEXIS 23155, at *27-*28.[4]

[4] For its part, AGA has refused to provide Gore with discovery regarding its upstream devices, and even has refused to produce information about ongoing clinical studies relating to commercialized devices that it contends are embodiments of the '738 patent. (*See, e.g.*, Goodin Ex. 6, Gore's First Set of Requests for Production at 4, ¶M (defining "Occlusion Devices" to include left atrial appendage closure devices); Goodin Ex. 7, AGA's Responses to Gore's First Requests for Production at 5, ¶14 (limiting the definition of "Occlusion Devices" to exclude left atrial appendage closure devices); Goodin Ex. 8, St. Jude Medical, Inc. Offer To Exchange Each Outstanding Share of Common Stock of AGA Medical Holdings, Inc. at 134 (confirming that AGA has a left atrial appendage occlusion device in development).) Under the circumstances, it would be inequitable to grant the relief sought by AGA. *See Eurand*, 266 F.R.D. at 85-86

When AGA filed its present motion, the only multi-wire septal occluder devices that Gore has received regulatory approval to market is the GORE® Septal Occluder medical device.[5] AGA will have the opportunity in a different lawsuit that is already pending to obtain the discovery it now seeks to compel here, as discussed in Section C below. That lawsuit is actually about the GORE® Septal Occluder medical device, and the discovery is proper in that lawsuit.

Moreover, AGA's assertion that the information about the multi-wire device is relevant to the issues of acceptable non-infringing alternatives is off base. (Dkt. 46 at 12.) Gore has not asserted that the GORE® Septal Occluder medical device is a non-infringing alternative. If at some point, different devices become relevant to the issue of damages as non-infringing alternatives, Gore will certainly produce documents about those devices. *See Caritas*, 2006 US Dist LEXIS 94879, at *14-*15 (denying motion to compel discovery on services not accused of infringement and stating that discovery should be supplemented if any other service becomes relevant either as a non-infringing alternative or as an alleged infringing service).

(denying discovery request and explaining that whether discovery on the issue were to be opened or not, "both sides would be subject to the same requirement.")

[5] To the extent that other development devices exist, they remain non-discoverable upstream potential future medical devices. *See Microsoft Corp.*, 2001 U.S. Dist. LEXIS 23155, at *27-*28.

C. The discovery AGA seeks to compel here is relevant to issues in the Delaware Action and injecting those issues into this case will only cause unnecessary delay to the progress of this case.

The fact remains that the only device which AGA has specifically accused of infringement in the District of Minnesota is the GORE® HELEX® Septal Occluder device. There is, however, a forum for the discovery which AGA seeks to compel regarding the GORE® Septal Occluder device, and it is the District of Delaware. The GORE® Septal Occluder device is already the subject of litigation in the District of Delaware, and Gore intends to provide such discovery to AGA in that venue.[6]

The issues to be resolved in the Delaware Action differ from the issues in this case. As AGA acknowledges, the Delaware Action includes an additional patent, U.S. Patent No. 5,725,552. Consequently, the invalidity defenses in the Delaware action will differ from those in the present case. In fact, AGA itself acknowledged the differences between the claims of the two patents when it distinguished the '552 patent during the prosecution of the application that matured into the '738 patent.

The HELEX® Septal Occluder and GORE® Septal Occluder devices are also different, which lead to different factual issues relating to non-infringement. Some illustrative differences without limitation are: the HELEX® Septal Occluder device consists of a single nitinol wire frame, while the next generation GORE® Septal Occluder device has a 5-wire frame; and the HELEX® device has solid nitinol wires, while the GORE® Septal Occluder device does not. With different issues to be resolved in the case

[6] While AGA has filed a motion to dismiss or to transfer in the Delaware Action, those issues have no relevance to AGA's motion to compel in this case.

in the District of Delaware versus this case in the District of Minnesota, it makes the most sense in terms of efficiency to keep discovery separate in the two cases. Gore should not have to provide duplicative discovery in both suits.

Also, injecting these issues surrounding the new GORE® Septal Occluder device that are pending in the District of Delaware into this case will inevitably lead to unnecessary and unwarranted delay in the progress of this case. If AGA were now to seek to amend its complaint to accuse the GORE® Septal Occluder device, both AGA and Gore would have to prepare and exchange preliminary and final infringement claim charts for this different device. AGA may choose to add the '552 patent. Gore would thus also have to provide additional invalidity charts for the '552 patent in addition to invalidity charts for the '738 patent. In this case, at least seven months will have elapsed from the time AGA served its preliminary infringement claim charts (served January 18, 2011) until the time Gore provides its final noninfringement claim chart (currently due August 22, 2011). The time both parties would need for these additional infringement and invalidity charts could bring the rest of the case to a halt until those could be completed.

AGA has no basis for its stated concern that it might be precluded from litigating infringement of the new GORE® Septal Occluder device. (*See* Dkt. 46 at 4 n.4.) That new device already is being litigated in Delaware, and there is nothing standing in AGA's way of pursuing any infringement theories it desires in that forum. The new GORE® Septal Occluder device is not relevant to the issues to be resolved in this case and

injecting it into this case will only lead to inevitable delay in the progress of this case. Therefore, AGA's motion to compel should be denied.

CONCLUSION

For the foregoing reasons, Gore respectfully opposes AGA's motion to compel immediate discovery concerning the Milan development device disclosed at the 8th International Workshop on Interventional Pediatric Cardiology in Milan, Italy.

Dated: July 12, 2011

Respectfully submitted,

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